

EXHIBIT 17

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UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

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In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

Civil Action No. 16-cv-4187

(JNE/FLN)

This Document Relates To:

Gareis v 3M Co., et al

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DEPOSITION OF BRADLEY P. PRESNAL, M.D.

VOLUME I, PAGES 1 - 183

DECEMBER 4, 2017

(The following is the deposition of BRADLEY P. PRESNAL, M.D., taken pursuant to Notice of Taking Deposition, via videotape, at the offices of Palmetto Health-USC Orthopedic Center Convenient Care Building, 101 Business Park Boulevard, in the City of Columbia, State of South Carolina, commencing at approximately 6:05 o'clock p.m., December 4, 2017.)

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<p style="text-align: right;">Page 14</p> <p>1 Q. Okay. How are instruments sterilized?</p> <p>2 A. I don't know if I can get into the technical</p> <p>3 part of it, but it basically is a high pressure, high</p> <p>4 temperature steam sterilizer.</p> <p>5 Q. Okay. Do you consider the hospital is</p> <p>6 competent to sterilize instruments?</p> <p>7 A. Yes.</p> <p>8 Q. Do you have any reason to believe that the</p> <p>9 instruments in Mr. Gareis's case were contaminated and</p> <p>10 caused the infection?</p> <p>11 A. Not -- Not that I remember. You know, the</p> <p>12 -- all the sterilized instruments have indicators that</p> <p>13 show whether they've reached the right temperature and</p> <p>14 pressure to show that they've gone through the cycle</p> <p>15 correctly, so that's always checked.</p> <p>16 Q. Any reason to believe that the implant was</p> <p>17 contaminated?</p> <p>18 A. No.</p> <p>19 Q. Do you engage in skin antisepsis? I think</p> <p>20 you touched on that a moment ago.</p> <p>21 A. Yeah. We probably started this in 2005,</p> <p>22 maybe earlier. We have patients do Hibiclens showers</p> <p>23 the night before and the morning of. So they take a</p> <p>24 shower with a special antibiotic soap the night before</p> <p>25 surgery, the morning they come in, and then we -- for</p>	<p style="text-align: right;">Page 16</p> <p>1 A. So we typically have signs on the outer door</p> <p>2 saying, you know, don't come in unless you have to</p> <p>3 come in. We limit any traffic that has to come in</p> <p>4 must come in through the sterile -- sterile corridor.</p> <p>5 We don't allow traffic to come in from the out --</p> <p>6 outer design. If you look, the -- the OR's have an</p> <p>7 outer corridor and a inner sterile corridor so the</p> <p>8 traffic that does come into the room has to come</p> <p>9 through the sterile corridor.</p> <p>10 Q. Okay. Do you recall, in Mr. Gareis's case,</p> <p>11 whether there was any unusual movement in and out of</p> <p>12 the operating room?</p> <p>13 A. Not that I remember, no.</p> <p>14 Q. When staff members do have to come in during</p> <p>15 the surgery, do they utilize the sterile door?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question.</p> <p>18 A. Yes. We tell them they have to come in that</p> <p>19 way, and we -- you know, certainly there may be rare</p> <p>20 cases where somebody doesn't know or comes in, but</p> <p>21 it's very unusual.</p> <p>22 Q. Have any reason to believe that that</p> <p>23 protocol was not followed in this case?</p> <p>24 A. No.</p> <p>25 Q. Does the operating room theatre have a</p>
<p style="text-align: right;">Page 15</p> <p>1 the surgery we use a skin prep which is typically</p> <p>2 either Dur -- a DuraPrep or ChloroPrep. Both are</p> <p>3 alcohol based with either chlorhexidine or iodine</p> <p>4 component.</p> <p>5 Q. Is there anything done as far as prep of the</p> <p>6 skin goes before making your incision?</p> <p>7 A. So that's the -- that's the DuraPrep or</p> <p>8 ChloroPrep's put on the skin.</p> <p>9 Q. Uh-huh.</p> <p>10 A. And then we use Ioban, which is a thin kind</p> <p>11 of plastic-type membrane that sticks to the skin that</p> <p>12 seals the drapes or helps keep the drapes in place.</p> <p>13 Q. And do you cut through that when making your</p> <p>14 incision?</p> <p>15 A. Yes.</p> <p>16 Q. And what is that designed to do?</p> <p>17 A. Well it -- it -- it's designed to cut on --</p> <p>18 or to cut down on the amount of bacteria migration to</p> <p>19 the skin, to -- to the edge of the incision.</p> <p>20 Q. Okay. When you make your incision do you</p> <p>21 use retractors to pull that away?</p> <p>22 A. Yes.</p> <p>23 Q. Let's talk about movement in and out of the</p> <p>24 operating room. Do you do anything to attempt to</p> <p>25 limit movement during these types of surgeries?</p>	<p style="text-align: right;">Page 17</p> <p>1 ventilation system?</p> <p>2 A. Yes.</p> <p>3 Q. And was this the type of system that</p> <p>4 introduces clean air into the OR?</p> <p>5 A. As far as I know when we -- when we looked</p> <p>6 at this, especially when I was involved with the</p> <p>7 renovations, we looked a lot at the airflow because</p> <p>8 it's important with joint replacement, so -- because</p> <p>9 we looked at possibly installing laminar flow, which</p> <p>10 is a little bit controversial as to whether it reduces</p> <p>11 infection. But basically what laminar flow is a</p> <p>12 unidirectional high exchange, so we found that what</p> <p>13 they had was still high exchange unidirectional flow</p> <p>14 which is basically laminar flow, it's just not the</p> <p>15 name for it.</p> <p>16 Q. Okay. And why is it important to have</p> <p>17 unidirectional flow?</p> <p>18 A. Because there have been studies that show</p> <p>19 that turbulent flow increases your risk of infection.</p> <p>20 So you want the airflow to be top down so that it's</p> <p>21 not pulling up things from the ground, so it's always</p> <p>22 pushing things down towards the floor.</p> <p>23 Q. Is reducing particulates in the air</p> <p>24 something you care about as the orthopedic surgeon?</p> <p>25 A. Sure.</p>

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<p>1 Q. Let's talk a little bit about the -- the</p> <p>2 implant itself. What type of implant did you put in</p> <p>3 Mr. Gareis?</p> <p>4 A. It was a -- a system from DePuy. The stem</p> <p>5 was a CORAIL stem. The typical implant that I use</p> <p>6 with that, the acetabular component is a PINNACLE. It</p> <p>7 had a polyethylene liner, Ultrex liner, and then he</p> <p>8 had a 40 millimeter metal head.</p> <p>9 Q. Okay. So it was not a metal-on-metal</p> <p>10 system?</p> <p>11 A. No.</p> <p>12 Q. Is the implant sterile before you place it?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. So when you place an implant for</p> <p>15 doing a total hip such as Mr. Gareis, how is it that</p> <p>16 you get the implant from the packaging into the</p> <p>17 patient?</p> <p>18 A. So typically there is a two-stage</p> <p>19 packaging -- packaging for all sterile implants,</p> <p>20 there's an outer portion that the scrub nurse will</p> <p>21 open and hand it to the scrub tech, so they handle it</p> <p>22 from off side the -- out of the sterile field onto the</p> <p>23 sterile field. Then there's another package that the</p> <p>24 scrub nurse or scrub tech will open to expose the</p> <p>25 implant so that you can implant it.</p>	<p>1 that point we had switched from staples to doing --</p> <p>2 Well let me make sure I'm telling you right because</p> <p>3 I'm not sure of the time we switched that. (Witness</p> <p>4 reviewing documents.) No, we did use staples in his</p> <p>5 case. We've gotten away from staples as well.</p> <p>6 Sterile dressings. We tell them not to</p> <p>7 shower for the first -- when we're using staples, for</p> <p>8 the first three days. So those are our sort of</p> <p>9 standard measures.</p> <p>10 Q. As you recall, was Mr. Gareis typically a</p> <p>11 compliant patient?</p> <p>12 A. Yes.</p> <p>13 Q. Do you have any reason whatsoever to believe</p> <p>14 that you or your staff failed to follow all the</p> <p>15 protocols that you just described?</p> <p>16 A. No. I think, you know, at that point we're</p> <p>17 pretty regimented with how we approach hip and knee</p> <p>18 replacement so we were doing all the things that we</p> <p>19 knew to do back then.</p> <p>20 Q. Okay. We're here because of a</p> <p>21 patient-warming device, want to talk to you a little</p> <p>22 bit about patient warming.</p> <p>23 You understand it's become common practice</p> <p>24 to warm patients during surgery; --</p> <p>25 A. Yes.</p>
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<p>1 Q. And then how do you physically get it out of</p> <p>2 the package into the -- into the patient?</p> <p>3 A. So we try and use as little touch -- no</p> <p>4 touch when we can. Some things it's almost impossible</p> <p>5 to do that. So for the acetabular component there's a</p> <p>6 handle that is attached, usually screws into the</p> <p>7 socket part, and that is your impactor, you use the</p> <p>8 handle, again trying not to touch the component as</p> <p>9 much as we can, place that in and -- and basically</p> <p>10 hammer it into place. For the stem, same thing;</p> <p>11 there's a handle that either screws in or locks onto</p> <p>12 the stem part and it is hammered into the femur, or</p> <p>13 impacted.</p> <p>14 Q. Okay. And did you do that in Mr. Gareis's</p> <p>15 case?</p> <p>16 A. Yes.</p> <p>17 Q. Are there any other infection control</p> <p>18 measures that we haven't talked about that you or the</p> <p>19 OR staff follows?</p> <p>20 A. Well we do -- the antibiotics are, you know,</p> <p>21 twenty -- are before surgery. The timing of that's</p> <p>22 critical so we try and do that within 30 minutes to an</p> <p>23 hour of cut time. We keep people on prophylactic</p> <p>24 antibiotics in the hospital for 24 hours IV</p> <p>25 antibiotics. We use, you know, sterile dressings. At</p>	<p>1 Q. -- right?</p> <p>2 Do you know what it's intended to do?</p> <p>3 A. I think the -- the basis is that they have</p> <p>4 shown -- there's some studies that show that keeping a</p> <p>5 patient warm decreases infection. From -- From my</p> <p>6 reading that is mainly in the general surgery realm.</p> <p>7 As far as I know, there's not a lot of published data</p> <p>8 in the orthopedic realm on that.</p> <p>9 Q. Well you bring up a good point.</p> <p>10 Do you know whether there's any solid</p> <p>11 evidence that supports the benefit of using patient</p> <p>12 warming during a total knee or total hip surgery?</p> <p>13 A. Not -- Not that --</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question, also lack of foundation.</p> <p>16 A. Not that I've read, no.</p> <p>17 Q. Okay. Do you subscribe to any orthopedic</p> <p>18 journals?</p> <p>19 A. Yes.</p> <p>20 Q. Or any general medical journals?</p> <p>21 A. Yes.</p> <p>22 Q. Do you feel like you keep abreast of the</p> <p>23 latest developments regarding orthopedic surgery?</p> <p>24 A. So I try to, and the other thing I typically</p> <p>25 do is I try and make it to the national meeting as</p>

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1 A. I wouldn't --
 2 MR. HODGES: Objection, form.
 3 A. -- say "infinite," but there are a lot of --
 4 there are several different ways, again depending on
 5 which -- if you divide it into time frames. That's
 6 how I think of it. Intraoperative, perioperative, and
 7 again perioperative can be different depending on who
 8 is making that definition of the timeframe, or late
 9 infection, chronic infection which could be a
 10 hematogenous spread, some type of infection somewhere
 11 else in the body goes there. And that could be any
 12 type of infection, although the typical ones are going
 13 to be some type of septic episode where they've had an
 14 infection somewhere else but they get bacteria in the
 15 blood and it goes to the hip.
 16 So I would consider all those -- they're
 17 different sources, but that's all one type of
 18 infection. Again there's lots of different sources it
 19 could come from, but it's sort of one way to get
 20 there, hematogenous spread through the blood.
 21 Q. Now earlier, when Mr. Hodges was asking you
 22 questions, you said something about the hospital was
 23 evaluating airflow, or you were -- maybe it was your
 24 group.
 25 A. Right. Right.

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1 Q. What prompted that?
 2 A. So when we were adding the new ORs, one of
 3 our discussions was, since we knew we were going to be
 4 doing a high percentage of joint replacements there,
 5 should we add laminar flow. So again it's a little
 6 bit controversial as to whether it actually decreases
 7 the risk; some people believe it does, some people
 8 don't. But what we found out through our research was
 9 laminar flow is almost a trademark. It is a
 10 unidirectional flow with a high exchange rate. So you
 11 can actually have the same thing as laminar flow, but
 12 not have to buy laminar flow, if that makes sense.
 13 It's kind of like buying Coke, or going and buying
 14 generic cola. You can get the same thing, but you're
 15 just not paying for the name.
 16 So laminar flow, we found out, was really
 17 more of a brand. So what we wanted was a
 18 unidirectional flow so the air flows from the ceiling
 19 to the floor in one direction, doesn't go in multiple
 20 directions. So you have a air vent above the
 21 operative flow --
 22 Q. I think they call it a plenum, does that
 23 sound?
 24 A. It may be. I don't know. I can't get that
 25 technical. But this is what I learned in our

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1 evaluation, so.
 2 But what you wanted was a certain level of
 3 full-room exchanges per minute or per hour, I can't
 4 remember what the parameter was. So unidirectional
 5 flow, a certain number of changes per minute or per
 6 hour. And that's what we wanted was to make sure that
 7 we were -- at least the airflow in the room was of the
 8 quality of a laminar flow. So we looked at the rooms
 9 that we currently used and the new rooms to make sure
 10 we were going to get that type of airflow in all of
 11 the rooms.
 12 Q. And the -- the downward flow from the
 13 ceiling, where does it go out?
 14 A. I can't know that I can answer that. So it
 15 goes straight down and you hope it goes away from the
 16 operative field. That's what you hope.
 17 Q. Okay. You're not aware of the location of
 18 any vents on the --
 19 A. I -- I assume there is, but I don't really
 20 know.
 21 Q. You described a door leading to a -- the --
 22 I think you described it as a sterile corridor.
 23 A. Sterile core, yes.
 24 Q. And when you used the words "the sterile
 25 core," the corridor itself is not sterilized; right?

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1 MR. HODGES: Objection, form.
 2 A. No. It's just more -- more barriers from
 3 the outside. So more doors to the -- between the
 4 operating room and the outside. So it's an extra door
 5 from the outside is what we're trying to use. And you
 6 can't go into that sterile core with your mask down.
 7 When I say you can't, you're instructed not to. If
 8 you're in the sterile core your mask has to be up. So
 9 in the outside areas around the OR you can walk around
 10 without a mask, but in this part of the OR, the
 11 sterile core, you can only go in with head cover, mask
 12 and everything. So it's kind of like an operating
 13 room, but you don't do any surgery in there.
 14 Q. And to get from the OR to the doctor's
 15 lounge you go through the sterile core?
 16 A. Sterile core, yes.
 17 Q. Okay. So the procedure would be to wear
 18 head -- head covering and mask through that.
 19 A. Yes.
 20 Q. But once you get to the doctor's lounge you
 21 can take that off?
 22 A. You can take the mask off.
 23 Q. Take the mask off but not the head covering?
 24 A. Typically once you're back there you're
 25 going to keep the head cover on. You put it on first